## REMARKS

Claims 1-3, 7 and 8 are pending in this application. Claims 7 and 8 have been allowed. Claims 1-3 have been rejected. Claim 1 has been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

**I. Claim rejections under 35 USC §112**

The rejection of claims 1-3 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention has been withdrawn. The rejection of claims 1-3 under 35 U.S.C. 112, first paragraph, for the recitation of "spleen-derived" has been withdrawn.

Claims 1-3 have been rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way to as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner suggests that the recitation of "wherein said composition is deficient of T-cells" is not literally supported by the specification. The Examiner suggests that the specification provides general support for compositions wherein the stem cells can be obtained from spleen, however, fails to provide any specific description of what would be contained in the composition, in particular the exclusion of any one cell type like T cells. It is suggested that Example II provides for "[E]nriched B cell

populations" by deleting T-cells, but fails to support the breadth of the claims for myeloid-committed stem cells, rather it supports methods for isolating B-cells which are not myeloid committed stem cells. The Examiner suggests that while the skilled artisan may be capable of removing T cells from a given population, there is no guidance in the specification to this end for the isolation of a myeloid-committed stem cell, nor why or how this is excluded when processing cell samples from the spleen. Applicants respectfully disagree with this rejection.

In the paragraph bridging pages 20-21, Applicants describe the discovery, features and advantages of the cells of the present invention.

> "LPS-simulated, T cell-depleted spleen cells taken from (BALB/c x C57B1/6)F1 or C57B1/6 mice were infected by cocultivation with packaging cell line producing the N2 vector virus (Fig. 1) and adoptively transferred into lethally irradiated F1 recipient. Gene transduction was dependent upon LPS stimulation but independent of T cell depletion although T cell depletion results in a higher transduction efficiency."

As acknowledged by the Examiner, the specification teaches T cell depletion of a B cell population using monoclonal antibody Jlj (rat IgM anti-mouse Thy-1.2), plus complement. See the sentence bridging pages 17 and 18. However, contrary to the Examiner's suggestion, Applicants also disclose the isolation of T-cell depleted *spleen cells* from mice using monoclonal antibody Jlj and complement. See page 18, lines 18-23. Thus, Applicants have clearly disclosed the isolation of myeloid-committed stem cells obtained from spleen which are depleted of T cells. In an earnest effort to facilitate the prosecution of the present application, Applicants have amended

claim 1 to indicate that the claimed composition is depleted of T cells as literally supported by the specification at page 16, lines 6-7. In light of this amendment and accompanying remarks, Applicants respectfully believe that the written description requirement has been met and therefore request that this rejection be reconsidered and withdrawn.

**II. Claim rejections under 35 USC §102**

Claims 1-3 remain rejected under 35 U.S.C. 102(b) as being anticipated by Freas-Lutz et al. ((1994) *Exp. Hematol.* 22:857-65). Claims 1 and 2 also remain rejected under 35 U.S.C. 102(b) as being anticipated by Migita et al. ((1995) *Proc. Natl. Acad. Sci. USA* 92:12075-12079). The Examiner suggests that nothing in the claims nor the specification provides for more than a functional limitation that the myeloid-committed stem cell is capable of differentiating into myeloid lineages and that the M1 cells of Freas-Lutz et al. and the CD34+ cells of Migita et al. meet this functional requirement. It is suggested that Applicants' arguments that all the features now claimed are not taught by the cited references is not persuasive because it is not clear what these properties or features would be. It is suggested that because the instant specification does not specifically define what a myeloid-committed stem cell is, the broadest interpretation is that the cell is any cell with a restricted ability to become a differentiated cell of the myeloid lineage, and the M1 and CD34+ cells of Freas-Lutz et al. and Migita et al., respectively, meet

this interpretation. Applicants respectfully traverse this rejection.

MPEP 2131 indicates that "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, *i.e.*, identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The cited prior art references teach transduction of a bone marrow-derived cell line and transduction of CD34+ cells. The cited prior art references do not teach or suggest each and every element of the claimed composition. Applicants' claim is drawn to a composition comprising the presence of certain elements, *i.e.*, lipopolysaccharide-stimulated, transduced, myeloid-committed stem cells obtained from spleen, and a biological carrier medium; and the absence of certain elements, *i.e.*, T cells. The instant stem cells have the distinctive feature of being myeloid-committed, *i.e.*, of the myeloid lineage thereby monitoring for the presence of foreign bodies, providing protection against neoplastic cells, scavenging foreign material, and producing platelets (see page 13, lines 23-28) and the distinctive property of being phenotypically altered by LPS-stimulation (see pages 7 and 8 of Applicants'

response dated November 29, 2005). Moreover, the instant population of cells is depleted of T cells (see remarks concerning written description rejection).

Neither Freas-Lutz et al. nor Migita et al. teach the phenotypic features of the instant stem cells, *i.e.*, lipopolysaccharide-stimulated, transduced, myeloid-committed. Moreover, neither Freas-Lutz et al. nor Migita et al. teach a composition containing such stem cells in a biological carrier medium, wherein the composition is depleted of T cells. Because the cited references fail to teach or suggest all of these essential features of the instant composition, these references fail to anticipate present invention. It is therefore respectfully requested that these rejections be withdrawn.

**III. Allowable Subject Matter**

Applicants acknowledge the allowance of claims 7 and 8. However, because Applicants believe that the proposed claim amendments overcome the rejection of claims 1-3 under 35 U.S.C. §102 and §112, Applicants respectfully request reconsideration of claims 1-3 and allowance of all pending claims as presented herein.

**IV. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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